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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,856	04/10/2002	Olaf Weber	Le A 33 771	5595

7590 06/13/2005
Jeffrey M Greenman
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,856

Applicant(s)

WEBER ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

The request filed on March 29, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/029,856 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Applicant describes preferential uptake and concludes that targeting does not mean exclusivity to certain cells. Applicant states that the increased rate of penetration of the instant recombinant virus is indirect evidence that the gD protein is expressed on the surface of the virus.

Applicant's arguments and the data presented in the instant disclosure have been fully considered, but are found unpersuasive. Contrary to applicant's assertions, the results of the working example do not provide any evidence that gD is expressed on the surface of the virus. Half of the gD-recombinant paramyxoviruses penetrated MDBK cells after 7 minutes, whereas half of the wild-type viruses were able to penetrate MDBK cells after 20 minutes. Therefore,

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both types of viruses are able to penetrate MDBK cells, regardless of whether the virus contains the gD gene. Faster penetration of the recombinant does not provide sufficient evidence that the virus has different, or altered, targeting properties compared with the wild-type virus. Both the recombinant and wild-type viruses are able to penetrate the same cells.

Applicant states that the problems discussed by Galmiche et al. do not apply to the instant case and points to pages 13-16 of the instant disclosure.

However, pages 13-16 of the instant disclosure do not provide any evidence that gD is expressed on the surface of the recombinant parapoxvirus. To prove the expression of a single chain antibody on the viral surface, Galmiche et al. use FACS, PCR, plaque purification, western blot and sequencing analysis, see “production and isolation of recombinant virus” on page 3020 and the “Results” section. Unlike the teachings of Galmiche et al., there is no data present in the instant working example demonstrating that gD is expressed on the surface of the virus.

Applicant asserts that the instant invention retargets parapoxvirus to specific cells, tissues and organs, but offers no evidence to support this conclusion. It cannot be determined from the data provided whether the instant recombinant expresses gD on the surface of the virus.

However, even if gD is expressed on the surface, there is no evidence that the instant recombinants show preferential (or re-targeted) infection since the wild-type virus and the recombinant infect the same cells. It is reiterated that although Galmiche et al. express a single chain antibody on the surface, Galmiche et al. do not observe preferential infection. The data of Galmiche et al. indicate other yet-to-be identified factors affecting poxvirus infection that have not been alleviated by the teachings provided in the instant disclosure. The instant disclosure also does not address problems of retargeting different forms of poxviruses that have different

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mechanisms of penetration into host cells, discussed by Boulanger et al. and Vanderplasschen et al. It has also not been demonstrated whether alteration of surface proteins impairs viral dissemination and infectivity, discussed by Dallo et al. For these reasons, it is maintained that the instant claims would require an undue quantity of experimentation for one skilled in the art.

Conclusion

This is an RCE of applicant's earlier Application No. 10/009,856. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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